SAFETY DATA SHEET

Polidocanol Injectable Foam

Revision date: Feb 20
Version no. 11

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY/UNDERTAKING

1.1 Identification of the substance/preparation

Product name Polidocanol Injectable Foam
Synonyms Varithena™, Polidocanol Endovenous Microfoam (PEM)

1.2 Use of the substance/preparation

Description Two canister gas system linked by a connector which on activation, provides a mechanism for oxygen gas transfer from one canister into a second canister. The second canister contains Polidocanol solution and carbon dioxide gas.

Use The final product is for sclerotherapy treatment.

1.3 Company/undertaking identification

Provensis Ltd
Lakeview,
Riverside Way,
Watchmoor Park
Camberley,
Surrey,
GU15 3YL
UK

1.4 Emergency telephone

Within the US (US Toll Free): 877-377-3784

Outside the US (Canada) +1 303-389-1204

For chemical emergency, spill, leak, fire, exposure or accident call above numbers day or night

SAFETY DATA SHEET

Polidocanol Injectable Foam

Revision date: Feb 20
Version no. 11

2. HAZARDS IDENTIFICATION

The product as supplied is 2 self-contained gas canisters. Under normal use and without damage these do not present a health or environmental hazard.

POLIDOCANOL CANISTER

Classification	Compressed gas
GHS Pictograms	
Signal Word	Warning
Hazard Statement	H280: Contains gas under pressure; may explode if heated
Precautionary Statement Storage	P403 - Store in a well-ventilated place. P410 - Protect from sunlight.

OXYGEN CANISTER

Classification	Compressed gas	Category 1
GHS Pictograms		
Signal Word	Warning	Danger
Hazard Statement	H280: Contains gas under pressure; may explode if heated	H270: May cause or intensify fire; oxidizer
Precautionary Statement Storage	P403 - Store in a well-ventilated place. P410 - Protect from sunlight.	P220 - Store away from combustible materials.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Composition

Components Name	Volume Per can (ml)	CAS Number	EU Inventory Number	Classification
CARBON DIOXIDE		124-38-9	204-696-9	Compressed gas
ETHANOL 96 % EP	0.60	64-17-5	200-578-6	Flammable liquid Category 2
Polidocanol solution	18	7732-18-5	231-791-2	Not classified

Charged with Carbon Dioxide to a pressure of 1.2 bar absolute
Contains other trace elements which do not affect the hazard classification of the product.

OXYGEN CANISTER

Components Name	Weight %	CAS Number	EU Inventory Number	Classification
OXYGEN	100	7782-44-7	231-956-9	Compressed gas Oxidizer Category 1

Charged with oxygen to a pressure of 5.4 bar absolute

4. FIRST AID MEASURES

General Seek medical advice if adverse symptoms occur and persist and in case of prolonged exposure.

Inhalation Move exposed person to fresh air at once.

Eye contact Promptly wash eyes with plenty of water.
Ensure contact lenses are removed prior to rinsing

Skin contact Wash skin immediately with soap and water.

Ingestion Rinse mouth thoroughly with water

5. FIRE-FIGHTING MEASURES

General hazard	High oxygen concentrations will accelerate combustion. Canisters may rupture from pressure build up when exposed to a fire situation or excessive heat.
Extinguishing media	Use extinguishing media appropriate for surrounding fire (i.e. water spray or regular foam, CO2, dry powder)
Extinguishing media to avoid	Non known
Special firefighting instructions	Containers close to fire should be removed or cooled with water. Beware of exploding gas canisters that are exposed to fire or excessive heat.
Firefighting equipment	As in any fire, wear approved, positive-pressure, self-contained breathing apparatus and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	Wear protective clothing as detailed in Section 8.
Environmental precautions	In case of Polidocanol canister release do not let product enter drainage system, surface and ground-water and soil (precautionary)
Clean-up methods	Leaking gas canisters should be vented to the open air or well ventilated area, away from combustible or flammable materials. Absorb residual fluid onto a paper towel or similar.

7. HANDLING AND STORAGE

7.1 Handling	Warning pressurized containers. Do not puncture, pierce or burn even when apparently empty. Do not spray on a naked flame or incandescent material. **OXYGEN CANISTER** Oxidising; Avoid Contact with combustible materials may cause fire.
7.2 Storage	Store at or below 86^{o}F (30^{o}C) Do not refrigerate or freeze Avoid storage in direct sunlight or heat. Protect from frost. Keep away from all sources of ignition.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limit value	Not available
8.2 Exposure control	Not required in the quantities concerned and in consideration of the intended use for the device. The POLIDOCANOL GAS CANISTER contains asphyxiant gases, under extreme circumstances in an enclosed space breathing may become difficult, if such a situation arises, provide general ventilation by opening available doors and/or windows.
8.2.1 Occupational exposure control	
Respiratory protection	Not required.
Eye Protection	Wear safety glasses or vented safety goggles, when there is a risk of eye contact.
Skin protection	Wear rubber gloves when there is a risk of skin contact.
Hygiene practices	Do not eat or drink while using this product. Wash hands after using this product.
8.2. Environmental exposure control	Avoid release to the environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information

Physical state	gas/liquid (polidocanol canister), gas (oxygen canister).
Colour	colourless
Odour	odourless

9.2 Important health, safety and environmental information

POLIDOCANOL CANISTER (Prior to Charging)
Solution of polidocanol charged with Carbon Dioxide approximately 1.2 bar absolute.

POLIDOCANOL CANISTER (After Charging)
Solution of polidocanol charged with a Carbon Dioxide/Oxygen gas mix (approximately 35:65 vol:vol) to pressure of approximately 3.3 bar absolute.

OXYGEN CANISTER (Before Charging)
Oxygen gas to pressure of approximately 5.4 bar absolute

OXYGEN CANISTER (After Charging)
Oxygen gas to pressure of approximately 3.3 bar absolute.

10. STABILITY AND REACTIVITY

Stable under normal conditions of use.

Materials to avoid	None known
Conditions to avoid	Keep away from combustible material and all sources of ignition. Pressurised container: protect from sunlight and do not expose to temperatures exceeding 50°C.

11. TOXICOLOGICAL INFORMATION

Available data for the dangerous components:

Acute oral toxicity (exp.) :	LD50 rat = 1260 mg/kg (Polidocanol CAS 68439-49-6) (1) LD50 mouse = 3450 mg/kg (Ethanol) (2) LD50 rat = 7060 mg/kg (Ethanol) (3)
Acute dermal toxicity (exp.) :	LD0 rabbit = 20000 ppm/10H (Ethanol) (4)
Acute inhalation toxicity (exp.) :	DL50 mouse = 39 gm/m3/4H (Ethanol) (5) DL50 rat = 20000ppm/10H (Ethanol) (4)
Skin irritation (exp.) :	No data available
Eye irritation (exp.) :	No data available
Skin sensitisation (exp.) :	No data available
Toxicity after prolonged exposure (exp.) :	No data available

CMR Effects

Mutagenicity (exp.) :	Ames test (Ethanol) negative (6) Mouse lymphoma (Oxygen) positive (7)
Cancerogenesis:	Not classifiable as a human carcinogen (Ethanol) (8)

12. ECOLOGICAL INFORMATION

Not considered as an environmental hazard.

Log Pow octanol/water (Ethanol) = - 0.31

13. DISPOSAL CONSIDERATIONS

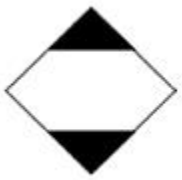
Disposal Methods	Dispose of in accordance with local regulations as aerosol waste. Observe all local laws and regulations.

14. TRANSPORT INFORMATION

For Transport, within, to or flying over The United States

Note Product Canister is not classified for transport only oxygen canister.

UN 2037 – Limited Quantities



DOCUMENTATION for sea transport only
UN2037, Receptacles, small, containing gas (gas cartridges), 2.2, 5.1 Limited Quantities.

Air Transport (Special precautions required for air transport over United States)

For air transport – UN2037, Receptacles, small, containing gas (gas cartridges), 2.2, 5.1 Limited Quantities.

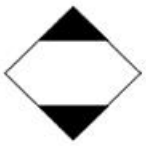
UN2037, Receptacles, small, containing gas, 2.2, 5.1.
Proper Shipping Name: Receptacles, small, containing gas *or* gas cartridges *(oxidising) without release device, not refillable and not exceeding 1 L capacity*

UN2037

For All Jurisdictions Apart from The United States

Note Product Canister is not classified for transport only oxygen canister.

UN 1950 – Limited Quantities



DOCUMENTATION for sea transport only
UN 1950 Class 2.2 Aerosols, non-flammable, (each not exceeding 1 L capacity), 2.2, 5.1 Limited Quantities,

Air Transport

For air transport – UN 1950 Class 2.2 Aerosols, non-flammable, (each not exceeding 1 L capacity), 2.2, 5.1 Limited Quantities,

15. REGULATORY INFORMATION

US Regulations - Oxygen
TSCA 8(a) IUR: Partial exemption
United States inventory (TSCA 8b): This material is listed or exempted.
SARA 302/304/311/312 extremely hazardous substances: No products were found.
SARA 302/304 emergency planning and notification: No products were found.
SARA 302/304/311/312 hazardous chemicals: Oxygen
SARA 311/312 MSDS distribution - chemical inventory - hazard identification:
Oxygen: Fire hazard, Sudden release of pressure, Delayed (chronic) health hazard

SAFETY DATA SHEET

Polidocanol Injectable Foam

Revision date: Feb 20
Version no. 11

EC Directives
The Safety Data Sheet is prepared according to Annex II of Regulation no. 1907/2006 (REACh) and the classifications is in accordance with the Directives 67/548/EEC and 1999/45/EC .

16. OTHER INFORMATION

Version No. 11
Revised section 1.4 New Emergency numbers
Disclaimer
This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how handling the material. The responsible of this document cannot warn of all potential dangers of use or interaction with other chemicals or materials. It is the user's responsibility for the product's safe use, the product's suitability for the intended use and the product's safe disposal.
No representation or warranties, either expressed or implied, of merchandability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers.